

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of MENDRICK *et al.*

Confirmation No.: 1108

Serial No.: 09/917,800

Group Art Unit: 1631

Filed: July 31, 2001

Examiner: M. I. Miller

For: MOLECULAR TOXICOLOGY MODELING

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**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(c)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56, Applicant(s) hereby submits the following information in conformance with 37 C.F.R. §§1.97 and 1.98.

- [X] Pursuant to 37 C.F.R. §1.98, a copy of each non-US patent document cited in the attached Form PTO/SB/08 is enclosed.
- [X] No copies of any U.S. patents or U.S. patent application publications listed on the attached Form PTO/SB/08 are being provided pursuant to 37 C.F.R. §1.98.
- [X] The present application and its related applications generally disclose toxicology modeling of various tissues or cells, *e.g.*, heart, kidney, liver, or primary hepatocytes using gene expression data. As such, some of the nucleic acid sequences disclosed in this application may overlap with those disclosed in other related applications. For the Examiner's convenience, a list of the co-pending applications is presented below.

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
10/501,933	Molecular Hepatotoxicology Modeling	Jan. 31, 2003	Liver
11/059,535	Molecular Toxicology Modeling	Feb. 17, 2005	Liver
10/152,319	Molecular Toxicology Modeling	May 22, 2002	Liver

APPLICATION SERIAL NO.	TITLE	APPLICATION DATE	TISSUE
10/301,856	Molecular Nephrotoxicology Modeling	Nov. 22, 2002	Kidney
10/515,325	Molecular Nephrotoxicology Modeling	Nov. 24, 2003	Kidney
11/036,196	Molecular Toxicology Modeling	Jan. 18, 2005	Kidney
10/191,803	Cardiotoxin Molecular Toxicology Modeling	Jul. 10, 2002	Heart
10/338,044	Molecular Cardiotoxicology Modeling	Jan. 8, 2003	Heart
10/541,937	Molecular Cardiotoxicology Modeling	Jan. 8, 2004	Heart
10/357,507	Primary Rat Hepatocyte Toxicology Modeling	Feb. 4, 2003	Hepatocyte
10/515,373	Primary Rat Hepatocyte Toxicity Modeling	Aug. 9, 2004	Hepatocyte
10/580,423	Methods For Molecular Toxicology Modeling	Nov. 24, 2004	General
11/547,759	Hepatotoxicity Molecular Models	Apr. 7, 2005	Liver
11/600,759	Cardiotoxin Molecular Toxicology Modeling	Nov. 17, 2006	Heart

[X] In particular, the following publications were cited by the U.S. Patent Examiner in U.S. application 10/152,319:

1. "nephrotoxic" definition, Merriam-Webster online dictionary, 2005, on the world wide web at <http://www.m-w.com/cgi-bin/dictionary?Book=Dictionary&va=nephrotoxic>
2. Yamaki *et al.* Cellular mechanism of lithium-induced nephrogenic diabetes insipidus in rats. American Journey of Physiology Renal Physiology, 1991. Vol. 262, F505-F511

In the list above, References 1-2 are listed herewith on the attached Form PTO/SB/08.

[X] The following publication was cited by the Examiner in U.S. application 10/301,856:

1. Konstandi *et al.* Stress-mediated modulation of B(alpha)P-induced hepatic CYP1A1: role of catechomaines, 2004 Chemico-Biological Interactions, vol. 147

This reference is listed herewith on the attached Form PTO/SB/08.

- [X] The following publication was cited by the Examiner in U.S. application 10/191,803:

U.S. 6,461,807

This reference is listed herewith on the attached Form PTO/SB/08.

- [X] The following publications were cited by the Examiner in U.S. application 10/357,507:

1. U.S. 6,203,987
2. Peng *et al.* JBC, 271(6):3324-3327
3. GenBank Acc. No. AA799479 (4/30/1998)
4. GenBank Acc. No. AI177366 (1/20/1999)
5. GenBank Acc. No. M25823 (4/27/1993)
6. GenBank Acc. No. AA891812 (1/25/1999)

References 1-6 are listed herewith on the attached Form PTO/SB/08.

- [X] References were also cited in related or corresponding foreign applications. The following publications were cited in a foreign search or examination report corresponding to PCT/US01/23872:

1. Raburn *et al.*, "Stage-specific expression of B Cell Translocation Gene 1 in rat testis," *Endocrinology* 136(12):5769 - 5777, 1995
2. GenBank Accession No. L26268, Raburn *et al.*, "Rattus norvegicus anti-proliferative factor (BTG1) mRNA," January 26, 1996
3. Bissig *et al.*, "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," *J Biol. Chem* 269(4):3017-3021, 1994
4. GenBank Accession No. L23413, Bissig *et al.*, "Rattus norvegicus sulfate anion transporter (sat-1) mRNA," April 12, 1994
5. WO 00/12760
6. Farr *et al.*, "Concise review: gene expression applied to toxicology," *Toxicol Sci* 50(1):1-9, 1999
7. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153 - 159, 1999

In the list above, references 3 and 5-7 have been considered by the Examiner in Applicants' previously submitted IDS. References 1, 2 and 4 are listed on the attached Form PTO/SB/08.

- [X] The following publications were cited in a foreign search or examination report corresponding to EP 01959321.9:

1. Markovich *et al.*, "Heavy metals mercury, cadmium, and chromium inhibit the activity of the mammalian liver and kidney sulfate transporter sat-1," *Toxicol. Appl. Pharmacol.* 154:181-187 (1999)
2. WO 99/58670
3. WO 93/01205
4. WO 99/43345
5. Berberner *et al.*, "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (*Onchorhynchus mykiss*) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," *Biomarkers* 4: 214-228 (1999)
6. Bogdan, "Human carbon catabolite repressor protein (CCR4)-associative factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," *Biochem. J.* 336:471-481 (1998)

References 1-6 are listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/03194:

1. U.S. 6,218,122
2. U.S. Publication 2001/0049139

References 1-2 are listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to Canadian application 2,447,357:

1. WO 01/32928, 05/11/01, Far *et al.*
2. Fielden *et al.* Changes and limitations of gene expression profiling in mechanistic and predictive toxicology, *Toxicol. Sci.* 60: 6-10 (2001)
3. Affymetrix Rat Toxicology U34 Datasheet, released 08/99

In the list above, references 1-2 have been considered by the Examiner in Applicants' previously submitted IDS. Reference 3 is listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02771863.4:

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.

5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

In the list above, references 1, and 4-9 have been considered by the Examiner in Applicants' previously submitted IDS. References 2-3 are listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US02/16173:

1. U.S. 6,228,589
2. U.S. 6,365,352
3. U.S. 6,403,778
4. Kim *et al.*, Fumonisin B1 induces apoptosis in LLC_{PK1} renal epithelial cells via a sphinganine and calmodulin dependent pathway. *Toxicology and Applied Pharmacology* 176:118-126 (2001)
5. Yang *et al.*, Differential regulation of COX-2 expression in the kidney by lipopolysacc: role of CD14. *Am J Physiology* 277(1):F10-F16 (1999)
6. Pfeffer *et al.*, Xanthine dehydrogenase and xanthine oxidase activity and gene expression in renal epithelial cells. *J Immunology* 153(4):1789-1797 (1994)

References 1-6 are listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US03/37556:

1. U.S. Publication 2002/0142284, 10/03/2002, Raha *et al*
2. WO 94/17208
3. WO 97/13877

In the list above, references 2-3 have been considered by the Examiner in Applicants' previously submitted IDS. Reference 1 is listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to EP 02806804.7:

1. WO 01/32928, 05/10/2001
2. Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)
3. Bulera, S.J., *et al.*, RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. *Hepatology*, 33:1239-1258, (2001)
4. Nuwaisyr *et al.*, "Microarrays and toxicology: the advent of toxicogenomics," *Molecular Carcinogenesis* 24(3):153-159, 1999.
5. Burczynski *et al.*, Toxicogenomics-based discrimination of toxic mechanism in hepg2 human hepatoma cells. *Toxicol. Sci.*, 58: 399-415 (2000)
6. Burchiel *et al.*, Analysis of genetic and epigenetic mechanisms of toxicity potential roles of toxicogenomics and proteomics in toxicology. *Toxicol. Sci.*, 59: 193-195 (2001)
7. WO 97/13877
8. WO 01/25473
9. WO 99/27090

In the list above, references 1, 4-9 have been considered by the Examiner in Applicants' previously submitted IDS. References 2-3 are listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/025646:

1. Wilson, *et al.* Exploring drug-induced alterations in gene expression in mycobacterium tuberculosis by microarray hybridization. *PNAS* 96:12833-12838 (1999)
2. Tao, *et al.*, Profiling of differently expressed apoptosis-related genes by cDNA arrays in human cord blood DC34+ cells treated with etoposide. *Experimental Hematology*, 31:251-2606 (2003)
3. Cadet, *et al.*, Distinct gene expression signatures in the striata of wild-type and heterozygous c-fos knockout mice following methamphetamine administration, *Synapse*, 44:211-2268 (2002)
4. He *et al.*, Histone deacetylase inhibitors induce remission in transgenic models of therapy-resistant acute promyelocytic leukemia., *Journal of Clinical Investigation* 108: 1321-1330 (2001)

Reference 1-4 are listed on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US04/039593:

1. U.S. Publication 2003/0124552, 07/03/2003, Lindemann *et al*
2. U.S. 6,132,969, 02/17/2000, Stoughton *et al.*

3. U.S. Publication 2003/0154032, 08/14/2003, Pittman *et al.*
4. U.S. Publication 2003/0028327, 02/06/2003, Brunner *et al.*
5. Hasegawa *et al.* Gan To Kagaku Ryoho 30: 325-33 (abstract)

References 1-5 are listed herewith on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/034780:

1. Boorman *et al.*, "Toxicogenomics, Drug Discovery, and the Pathologist," Toxicologic Pathology 30(1):15-27 (2002).
2. Harris *et al.*, "Comparison of basal gene expression profiles and effects of hepatocarcinogens on gene expression in cultured primary human hepatocytes and HepG2 cells," Mutation Research 539:79-99 (2004).
3. Gooderham *et al.*, "Molecular and genetic toxicology of 2-amino-1-methyl-6-phenylimidazo[4,5-*b*]pyridine (PhIP)," Mutation Research 506-507:91-99 (2001).
4. Hogstrand *et al.*, "Application of genomics and proteomics for study of the integrated response to zinc exposure in a non-model fish species, the rainbow trout," Comparative Biochemistry and Physiology Part B 133:523-535 (2002).

References 1-4 are listed herewith on the attached Form PTO/SB/08.

[X] The following publications were cited in a foreign search or examination report corresponding to PCT/US05/011532:

1. Kikuchi *et al.* Gene expression and activities of protein phosphatases 1 alpha, 2A, 2C in hepatocarcinogenesis and regeneration after partial hepatectomy. Cancer detection and prevention. 1997 vol.21(1): 36-43
2. Frazier *et al.* Predictive toxicodynamics: empirical/mechanistic approaches. Toxicology in Vitro, 1997, vol. 11: 465-472
3. Irizarry *et al.* Summaries of Affymetrix Gene Chip probe level data. Nucleic Acids Research, 2003, vol. 31, page e15
4. U.S. 6,153,421
5. U.S. 6,421,612
6. U.S. 5,858,659
7. Jakubczak *et al.* An oncolytic adenovirus selective for retinoblastoma tumor suppressor protein pathway-defective tumors. Cancer Research, 2003 vol. 63:1490-1499

References 1-7 are listed herewith on the attached Form PTO/SB/08.

This Information Disclosure Statement is filed within any one of the following time periods:

- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☐ before the mailing date of a first office action on the merits; or
- ☒ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.

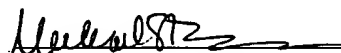
It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08 to the undersigned.

Respectfully submitted,
COOLEY GODWARD LLP

Dated: 12-13-2006

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PTO/SB/08A (07-05)
Approved for use through 07/31/2006. OMB 0651-0031

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	09/917,800
		Filing Date	07/31/2001
		First Named Inventor	Mendrick <i>et al.</i>
		Group Art Unit	1631
		Examiner Name	M.I. Miller
Sheet	1 of 6	Attorney Docket Number	GENE-035/09US

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
		Number-Kind Code ² (if known)				
	1.	US-6,421,612	07/16/2002	AGRAFIOTIS, <i>et al.</i>		
	2.	US-6,228,589	05/08/2001	BRENNER		
	3.	US-6,403,778	06/11/2002	CUNNINGHAM, <i>et al.</i>		
	4.	US-6,203,987	03/20/2001	FRIEND, <i>et al.</i>		
	5.	US-6,218,122	04/17/2001	FRIEND, <i>et al.</i>		
	6.	US-5,858,659	01/12/1999	SAPOLSKY, <i>et al.</i>		
	7.	US-6,132,969	02/17/2000	STOUGHTON, <i>et al.</i>		
	8.	US-6,153,421	01/27/1998	YANAGI, <i>et al.</i>		
	9.	US-6,365,352	04/02/2002	YERRAMILI, <i>et al.</i>		
	10.	US-6,461,807	10/08/2002	FRIEND, <i>et al.</i>		
	11.	US-2003/0028327	02/06/2003	BRUNNER, <i>et al.</i>		
	12.	US-2001/0049139	12/06/2001	LAGASSE, <i>et al.</i>		
	13.	US-2003/0124552	07/03/2003	LINDEMANN, <i>et al.</i>		
	14.	US-2003/0154032	08/14/2003	PITTMAN, <i>et al.</i>		
	15.	US-2002/0142284	10/03/2002	RAHA, <i>et al.</i>		
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		WO 99/58670	11/18/1999	Cadus Pharmaceutical Corporation, <i>et al.</i>		
		WO 93/01205	01/21/1993	The Salk Institute for Biological Studies		
		WO 99/43345	02/09/1999	Eisai Company, <i>et al.</i>		
		WO 01/32928	10/05/2001	Phase-I Molecular Toxicology, <i>et al.</i>		
OTHER – NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T ²
		Affymetrix Rat Toxicology U34 Datasheet, released 08/99 (PDF)				
		ANDERSSON, <i>et al.</i> , Toxicology, 135: 11-20 (1999)				
		ANTON, <i>et al.</i> , Cell Biochem. Biophys., 32: 27-36 (2000)				
		ARANO, <i>et al.</i> , Arzneimittelforschung, 46: 398-400 (1996)				
Examiner Signature		Date Considered				

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	09/917,800
		Filing Date	07/31/2001
		First Named Inventor	Mendrick et al.
		Group Art Unit	1631
		Examiner Name	M. I. Miller
Sheet	2 of 6	Attorney Docket Number	GENE-035/09US

OTHER – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BERBNER, <i>et al.</i> , "induction of cytochrome P450 1A and NDA damage in isolated rainbow trout (<i>Onchorhynchus mykiss</i>) hepatocytes by 2, 3, 7, 8-tetrachlorodibenzo p-dioxin," <i>Biomarkers</i> 4: 214-228 (1999)	
		BERGERON, <i>et al.</i> , <i>Xenobiotica</i> , 28: 303-312 (1998)	
		BISSIG, <i>et al.</i> , "Functional expression cloning of the canalicular sulfate transport system of rat hepatocytes," <i>J Biol. Chem</i> 269(4):3017-3021, 1994.	
		BOGDAN, "Human carbon catabolite repressor protein (CCR4)-associative factor 1: cloning, expression and characterization of its interaction with the B-cell translocation protein BTG1," <i>Biochem. J.</i> 336:471-481 (1998)	
		BOORMAN, "Toxicogenomics, Drug Discovery, and the Pathologist," <i>Toxicologic Pathology</i> 30(1):15-27 (2002).	
		BURCZYNSKI, <i>et al.</i> , <i>Toxicol. Sci.</i> , 58: 399-415 (2000)	
		BULERA, S.J., <i>et al.</i> , RNA expression in the early characterization of hepatotoxicants in wistar rats by high-density DNA microarrays. <i>Hepatology</i> , 33:1239-1258, (2001)	
		CADET, <i>et al.</i> , Distinct gene expression signatures in the striata of wild-type and heterozygous c-fos knockout mice following methamphetamine administration, <i>Synapse</i> , 44:211-2268 (2002)	
		CHEN, <i>et al.</i> , <i>J. Environ. Pathol. Toxicol. Oncol.</i> , 14: 83-99 (1995)	
		CORTON, <i>et al.</i> , <i>Biochimie.</i> , 79: 151-162 (1997)	
		D'MELLO, <i>et al.</i> , <i>Exp. Toxicol. Pathol.</i> , 51: 549-553 (1999)	
		Database Geneseq [online], "Sindbis virus genomic cDNA PCR primer SEQ ID NO:3," Database Accession No. AAZ92894, retrieved from EBI Accession No. GSN:AAZ92894 (2000)	
		DAVILA <i>et al.</i> , <i>Toxicology.</i> , 57: 267-286 (1989)	
		DELANEY & TIMBRELL, <i>Xenobiotica</i> , 25: 1399-1410 (1995)	
		FALZON, <i>et al.</i> , <i>Br. J. Exp. Pathol.</i> , 66: 527-534 (1985)	
		FAN, <i>et al.</i> , <i>J. Biol. Chem.</i> , 271: 24698-24710 (1996)	
		FARGHALI, <i>et al.</i> , <i>Methods Find. Exp. Clin. Pharmacol.</i> , 6: 449-454 (1984)	
		FIELDEN, <i>et al.</i> , Changes and limitations of gene expression profiling in mechanistic and predictive toxicology, <i>Toxicol. Sci.</i> 60: 6-10 (2001)	
		FORESTIER, <i>et al.</i> , <i>Biochem. Biophys. Res. Commun.</i> , 225: 377-383 (1996)	
		FRAZIER, JM, Predictive Toxicodynamics: Empirical/mechanistic approaches. <i>Toxicology in Vitro</i> , 1997. Pgs. 465-472, Vol. 11	
		GEIGER, <i>et al.</i> , <i>Agents Actions</i> , 38: Spec No: C69-72 (1993)	
Examiner Signature		Date Considered	

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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Complete if Known	
		Application Number	09/917,800
		Filing Date	07/31/2001
		First Named Inventor	Mendrick et al.
		Group Art Unit	1631
		Examiner Name	M. I. Miller
Sheet	3 of 6	Attorney Docket Number	GENE-035/09US

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OTHER – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		GenBank Accession No. L23413, BISSIG, <i>et al.</i> , "Rattus norvegicus sulfate anion transporter (sat-1) mRNA," April 12, 1994.	
		GenBank Accession No. L26268, RABURN, <i>et al.</i> , "Rattus norvegicus anti-proliferative factor (BTG1) mRNA," January 26, 1996	
		GenBank Acc. No. AA799479 (4/30/1998)	
		GenBank Acc. No. AA891812 (1/25/1999)	
		GenBank Acc. No. A1177366 (1/20/1999)	
		GenBank Acc. No. M25823 (4/27/1993)	
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		Filing Date	07/31/2001
		First Named Inventor	Mendrick et al.
		Group Art Unit	1631
		Examiner Name	M. I. Miller
Sheet	4 of 6	Attorney Docket Number	GENE-035/09US

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